KINAMED INCORPORATED

APR 0 5 2013

Traditional 510(k) Summary

Manufacturer: KINAMED® Incorporated
820 Flynn Road
Camarillo, CA 93012-8701
USA
Phone (805) 384-2748
FAX (805) 384-2792

Contact Person: Heather Neely, RAC
Senior Director of Quality Assurance and Regulatory Compliance
Kinamed®, Inc.
Phone (805) 384-2748 x210
FAX (805) 384-2792
email: hneely@kinamed.com

Date Prepared: July 11, 2012, revised February 15, 2013

DEVICE INFORMATION

Trade/Proprietary Name: NeuroPro® Low Profile Cranial Plating System 510(k)

Common Name: Cranial Plating System
Classification Name: Preformed alterable cranioplasty plate, 21 CFR 882.5320

Burr Hole Cover, 21 CFR 882.5250

Cranioplasty plate fastener, 21 CFR 882.5360

Class II
Device Product Code: GWO, Preformed alterable cranioplasty plate
GXR, Burr Hole Cover
HBW, Cranioplasty plate fastener

Predicate Devices: K964362 NeuroPro® Cranial Plating System
K982927 NeuroPro® Quick Tap® Bone Screws
K911936 OsteoMed® Fast-Flap™ Neuro Fixation System
K953385 Biomet® ThinFlap™ Lorenz® Plating System Neuro
K974785 OsteoMed® Auto-Drive Bone Screw

Product Description:
The NeuroPro® Low Profile Cranial Plating System provides rigid fixation of cranial bone flaps with a thin profile for reduced palpability. The system consists of bone screws and mating bone plates and panels with a beveled plate edge and thinner profile to reduce palpability. Malleable bone plates and panels are easily shaped by hand and/or with stainless steel instruments. The bone screws are used to secure various shapes of bone plates and panels to the cranium. The NeuroPro® Low Profile plates and panels are manufactured from Commercially Pure Titanium and meet all of the specifications of ISO 5832-2 or ASTM F-67. The NeuroPro® Low Profile screws are manufactured from 6Al/4V ELI (Extra Low Interstitial) Titanium Alloy and meet all of the specifications of ISO 5832-3 or ASTM F-136.

The NeuroPro® Low Profile Cranial Plating System is a modification of the standard NeuroPro® Cranial Plating System to be made thinner than those in the original submission (K964362), with exception of the hex panels which are the same thickness.

The NeuroPro® Low Profile Cranial Plating Screws are a modification of the standard NeuroPro® Quick Tap® Bone Screws to have a shorter screw head height than those in the original submission (K982927). The plates, panels and screws are similar in sizes, dimensions and identical in functionality as the standard NeuroPro® Cranial Plating System which was cleared as part of the original 510(k) submission (K964362).

The NeuroPro® Low Profile Cranial Plating System is identical to the standard NeuroPro® Cranial Plating System in terms of intended use, indications for use, material of construction, manufacturing process, functionality, compatibility of the plates and panels with all screw types, shelf life, biocompatibility, packaging and sterilization method.

Indications for Use:
The NeuroPro® Low Profile Cranial Plating System Family is intended for internal fixation of fractures and osteotomies of the cranial skeleton, internal fixation of cranial bone flap osteotomies and reconstruction of bony defects and deficits in the cranial skeleton.

The NeuroPro® Low Profile Cranial Plating System is not indicated for use in the spine or high load bearing applications.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the NeuroPro® Low Profile Cranial Plating System was conducted in accordance with various international standards and internal Kinamed methods.

All of the NeuroPro® Low Profile components are made of materials which conform to international and/or FDA recognized consensus standards for the type of material. All of these materials have a long successful history in similar neurosurgical implant applications.

The NeuroPro® Low Profile Cranial Plating System was tested as part of design verification/validation to Kinamed test methods with pre-defined acceptance criteria. As applicable, the testing was conducted on the worst case component size and option/design. Bone plates and panels were subjected to bend testing according to ASTM F67-06. Bone screw testing consisted of the following Kinamed test methods:

- Rate of Insertion (Amount of screw advancement per revolution)
- Ease of Insertion (Driving torque required per revolution)
- Torsional Strength
- Screwdriver Interface Integrity
- Simulated Use in Animal Bone

The testing met all acceptance criteria and verifies that the performance of the NeuroPro® Low Profile Cranial Plating System is substantially equivalent to the predicate devices.

Basis of Substantial Equivalence

The NeuroPro® Low Profile Cranial Plating System has the following similarities to the standard NeuroPro® Cranial Plating System (K964362) and NeuroPro® Quick Tap® Bone Screws (K982927):

- same intended use
- same indications for use
- same raw material
- same method of manufacture
- same design
- similar sizes and dimensions
- same type of mating components
- same shelf life
- same biocompatibility
- same sterilization and packaging methods

The new Low Profile System has some thinner plates/panels, shorter screw head height and is a differentiating color.

Conclusion:
The data and information provided in this submission support the conclusion that the NeuroPro® Low Profile Cranial Plating System is substantially equivalent to its predicate devices, standard NeuroPro® Cranial Plating System and Quick Tap® Bone Screws with respect to intended use, design, and operational principles. The use of low profile components is equivalent to that used in other cleared cranial fixation systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

Kinamed, Inc.
% Ms. Heather Neely
Senior Director of Quality Assurance
and Regulatory Compliance
820 Flynn Road
Camarillo, CA 93012

Re: K122049
Trade/Device Name: NeuroPro® Low Profile Cranial Plating System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Neely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical Medicine
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122049

Device Name: NeuroPro® Low Profile Cranial Plating System

Indications for Use:

The NeuroPro® Low Profile Cranial Plating System Family is intended for:

1. Internal fixation of fractures and osteotomies of the cranial skeleton.
2. Internal fixation of cranial bone flap osteotomies.
3. Reconstruction of bony defects and deficits in the cranial skeleton.

The NeuroPro® Low Profile Cranial Plating System is not indicated for use in the spine or high load bearing applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H. Nguyen
2013.04.05 13:35:35 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)
510(k) Number K122049